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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,375

Applicant(s)

GRUBER ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 15-23, 25-29, 31, 32, 34-36 and 46-61 is/are pending in the application.
- 4a) Of the above claim(s) 4, 31 and 57-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 15-23 and 25-28 is/are rejected.
- 7) ☒ Claim(s) 5, 29, 32, 34-36 and 46-56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed September 13, 2004. Amendments were made to the claims.

Claims 3-5, 15-23, 25-29, 31, 32, 34-36 and 46-61 are pending and under consideration in the instant application. Claims 4, 31 and 57-61 are withdrawn from consideration. Claims 3, 5, 15-23, 25-29, 32, 34-36 and 46-56 are under examination in the instant Application. Any rejection of record in the previous Office Action, mailed April 9, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Election/Restrictions

Applicant continues to traverse the restriction requirement to one sequence, SEQ ID NO: 22. Applicant argues that SEQ ID NOS: 4, 21 and 22 are “structurally different aspects of the same invention,” and that a search of three different structural elements would not be burdensome on the Office (see for example page 26 of Applicant’s response, second full paragraph).

It was clearly set forth in the Restriction requirement that the Office will search only a single nucleic acid sequence in an application, because each sequence represents a distinct nucleic acid sequence that must be searched individually. Applicant clearly recognizes that SEQ ID NO: 4, 21 and 22 represent distinct structures (see specifically page 26, lines 14-15 of

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Applicant's response). Because these structures are distinct, each of the sequences requires a different search, which the Office has established is burdensome. It is also noted that the individual sequences comprise much more than the common element (i.e., a Gbox), thus this single element does not sufficiently tie the structures together such that a search would not be burdensome. Specifically, a search of SEQ ID NO: 22 will not result in the identification of SEQ ID NO: 4, or SEQ ID NO: 21, because the sequences are sufficiently divergent from each other. Thus, multiple searches would be required to search the invention, which is a burden upon the Office.

Claim Objections

Claims 5, 29, 32, 34-36 and 46-56 remain objected to because of the following informalities: the claims continue to recite non-elected subject matter (i.e., SEQ ID NO: 4 and 21). Appropriate correction is required.

Claims 57-61 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be recited in the alternative. Specifically, claim 57 (and its dependent claims) continues to be dependent on claim 5 *and* claim 35 *and* claim 46, which are not recited in the alternative. See MPEP § 608.01(n). Accordingly, those claims have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Thomas, as recited in the previous Office Action. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds for traversal:

1. It is argued that Thomas does not teach “a chimeric promoter having a GATA box which confers light-regulatable expression on a transcription unit operably linked to said promoter” (see for example page 29 of Applicant's response, the penultimate line of the bridging paragraph).

Thus, it is concluded that Thomas cannot anticipate instant claim 15.

2. It is argued that a “cereal box” has a specific art-recognized term, defined as a motif containing a GCN4-like motif (GLM), and that Thomas does not teach such a motif in their promoter (see for example page 29 of Applicant's response, first full paragraph).

Applicant's arguments have been fully considered but are not found persuasive for the following reasons:

1. In the previous Office Action, the Office clearly indicated the location of at least one GATA box in the promoter taught by Thomas (see for example 7 of the previous Office Action). This GATA box began at –296 of the promoter element, and was thus located upstream of the transcription start site. Since Applicant has provided no other structural requirements on the

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GATA box, other than that it have the GATA sequence, this sequence must have the functional capacity to confer light-regulatable expression because it meets all of the structural requirements of the element. Applicant has provided no evidence as to why this GATA element does not have light-regulatable expression capabilities, thus the rejection of claim 15 is maintained until further showing that the GATA element in the promoter taught by Thomas does not have such light-regulatable properties.

2. The instant specification defines a “cereal box” as a “regulatory or functional motif or element which may confer seed-specific expression in at least wheat” (see page 14, lines 1-2 of the instant specification). Nowhere in this definition is there a requirement that the “cereal box” comprise a GCN4-like motif. Thus, Applicant’s contention that Thomas cannot anticipate instant claims 16-19 because they do not teach a GCN4-like motif in their promoter is unduly limiting in view of the definition set forth in the instant specification. While an applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning [See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)], where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim [*Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999)]. In the instant case, the much broader definition of “cereal box” is controlling in the interpretation of the claim, and the requirement for the “cereal box” to contain a GCN4-like motif is improper. Based on the showing in the previous Office Action that the HMWG promoter is wheat seed-specific, the Office maintains that Thomas teaches the presence

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of a "cereal box" in their promoter as per its broad definition in the specification (i.e., that the "cereal box" merely confer seed-specific expression). Should Applicant wish to limit their definition to comprise a GCN4-like motif, they should find support for such a limitation and amend the claims appropriately.

In conclusion, Applicant's arguments concerning the anticipation of claims 15-19 by Thomas are not convincing, and the previous rejection is maintained regarding said claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

New Grounds of Rejection, Necessitated by Amendment

Claims 20-23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (as cited previously) in view of Verdaguer *et al.* (*Plant Mol. Biol.* 37: 1055-1067, 1998; see entire document; henceforth Verdaguer). **This is a new rejection that is necessitated by amendment of the claims.**

Thomas teaches all of the elements set forth in the previous Office action. Specifically, Thomas teaches a chimeric promoter including an enhancer region from the HMWG gene Glu-D1-2 and a functional portion (although truncated) of a CaMV promoter. Thomas also teaches the presence of a "cereal box," a "G-box," a "GATA box," a "TATA box," a "GC-rich element"

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and a “P-box.” However, Thomas teaches the use of a truncated CaMV promoter which lacks an “as2 box” thereby failing to teach the use of an as2, as2/as1 or as1/as2 box.

Verdaguer teaches that the full length 35S CaMV promoter is “widely used in plant biotechnology and its functional organization is well described...[T]his promoter is highly active and directs constitutive gene expression in most tissues of transgenic plants” (see for example page 1055, right column).

It would have been obvious for the ordinary skilled artisan to combine the teachings of Thomas and Verdaguer because the full length CaMV promoter element is well described functionally and is used widely in the field of plant biotechnology (the field in which the teachings of Thomas are grounded), thus the skilled artisan would be working with the most commonly accepted elements of the field. The ordinary skilled artisan would have been motivated to combine the teachings of Thomas and Verdaguer to use the full length 35S CaMV promoter in order to use a promoter element that has the benefit of being well characterized, and therefore has the least possibility of eliciting an unexpected effect. Absent evidence to the contrary, the skilled artisan would have had a reasonable expectation of success when combining the Thomas and Verdaguer references.

Maintained Rejection

Claim 3 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas (as applied to claims 15-19, addressed above and in the previous Office Action) in view of Halford (as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Response to Arguments Concerning Claim Rejections - 35 USC § 103

Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds for traversal:

1. It is argued that the Halford reference provides no motivation for substituting the Glu-1-Dx5 promoter taught by Halford for the Glu-D1-2 promoter taught by Thomas in a chimeric promoter, thus there is no motivation to combine the reference in a *prima facie* manner (see for example page 31 of Applicant's response).

Applicant's arguments have been fully considered but are not found persuasive for the following reasons:

1. In the previous Office Action, the Office submitted that the ordinary skilled artisan would have been motivated to combine the Thomas and Halford references in order to produce a heterologous gene using a chimeric promoter (as taught by Thomas), wherein the promoter contains a promoter element that shows enhanced expression of heterologous genes (such as the Glu-1-Dx5 promoter taught by Halford). Thomas already uses a chimeric promoter containing a High Molecular Weight Glutein (HMWG) promoter element, and Halford merely provides another HMWG promoter element with enhanced expression activity. Thus, the motivation here is to simply substitute the enhanced promoter element taught by Halford into the chimeric promoter used by Thomas to express a heterologous gene, thereby resulting in an enhanced gene expression by the chimeric promoter of Thomas. Because the Halford promoter element has this relevant desirable property, the skilled artisan would be motivated to substitute it into the

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chimeric promoter of Thomas, with the expected benefit of enhancing expression from the chimeric promoter taught by Thomas. Applicant has provided no reason as to why the skilled artisan would not recognize this motivation, which necessarily results in the chimeric promoter of claim 3. As such, the rejection is maintained for the reasons set forth in the previous Office Action.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER